K040917

APR 2 9 2004

7 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. § 807.92.

1. The submitter of this premarket notification is :

Herbert van Dyk
Quality and Regulatory Senior Engineer
Philips Medizin Systeme Böblingen GmbH
Patient Monitoring Division
Cardiac Monitoring Solution Group
Hewlett Packard Str. 2
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Germany
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The summary was prepared on April 06 , 2004.

2. The name of this device is the PhilipsM1026B Anesthetic Gas Monitor for use with the Philips IntelliVue Family of Patient Monitors MP40/50/60/70/90, the Anesthesia Component Monitoring System M1176A and the Philips Viridia 24 System. The common name is the Philips Anesthesia Gas Monitor.
Classification names are as follows:

Regulation number	Classification name
868.1400	Carbon dioxide gas analyzer
868.1500	Enflurane gas analyzer
868.1620	Halothane gas analyzer
868.1700	Nitrous oxide gas analyzer
868.1720	Oxygen gas analyzer
868.2375	Breathing frequency monitor
Unclassified	Desflurane gas analyzer
Unclassified	Isoflurane gas analyzer
Unclassified	Sevoflurane gas analyzer

The unclassified gas analyzers for desflurane, isoflurane and sevoflurane are similar to the gases classified under 868.1500, enflurane, and 868.1620, halothane. Analysis of these gases has been cleared under the original M1026B AGM 510(k) no. K951127 and K982619

3. The above device is substantially equivalent to the PhilipsM1026A marketed pursuant to K951127, K982619, and K994188.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Mr. Herbert van Dyk
Quality and Regulatory Sensior Engineer
Philips Medizin Systeme Böeblingen GmbH
Cardiac Monitoring Solutions Group
Hewlett-Packard Str.2
71120 Böeblingen
GERMANY

Re: K040917
Trade/Device Name: Philips Anesthesia Gas Monitor, Model M1026B
Regulation Number: 21 CFR 868.1500 and 21 CFR 868.1620
Regulation Name: Halothane Gas Analyzer, Enflurane Gas Analyzer
Regulatory Class: II
Product Code: CBQ, CBS
Dated: April 6, 2004
Received: April 8, 2004

Dear Mr. van Dyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

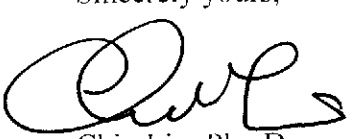
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Philips M1026B Anesthesia Gas Monitor

Indications for Use:

The M1026B Anesthesia Gas Module is intended to measure and monitor anesthesia gas contents in the ventilation circuitry of a patient and to provide this data to health care professionals in form readings, waves and alarms, via the Component Monitoring System, for the support of clinical decision making.

The device is indicated for use in health care facilities by health care professionals whenever there is a need for adult, pediatric and neonate patient anesthesia gas monitoring.

MRI Compatibility Statement: The M1026B is not intended for use in a MRI magnetic field

Prescription Use __Yes____ AND / OR Over-The-Counter Use __No____
(part 21 CFR 801 Subpart D) (part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040917

(Optional Format 3-10-98)

(Posted November 13, 2003)